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*Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
*Formerly Nonprescription Drug Manufacturers Association*



June 8, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: International Standard-Setting Activities; Codex Alimentarius Commission; Committee on Nutrition and Foods for Special Dietary Uses; Background Paper to Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin and Mineral Supplements – Docket No. 99N-0391 (64 Fed. Reg. 17397), CHPA Comments

Dear Sir or Madam:

On April 9, the Food and Drug Administration published the above-referenced notice requesting comments to be used by the U.S. delegate to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in a background paper for the CCNFSDU prior to considering the appropriateness of establishing guidelines for vitamin and mineral supplements through Codex.

The Consumer Healthcare Products Association is the national association representing manufacturers and distributors of nonprescription medicines and dietary supplements. Our 200 member companies across the manufacturing, distribution, supply and service sectors of the consumer healthcare industry make well-known vitamin and mineral supplements such as One-A-Day, Centrum, and many others.

**Summary.** The report on the September 21-25, 1998 CCNFSDU meeting already accurately crystallizes fundamentally different approaches to vitamin/mineral supplement regulation among countries – some with a food or food-oriented approach, and others with an approach more aligned with drugs. (See "Report of the Twenty-First Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses," September 21-25, 1998, paras. 41-45.) As FDA has noted in its report on Codex discussions of vitamin/mineral guidelines (see

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FDA Information Paper, September 8, 1997), we question whether a need really exists to proceed with the development of such guidelines. A combination of the different approaches is unlikely to satisfy the needs or concerns of any interested party. Given this seeming impasse, we urge the U.S. Government to include the option of moving on to other areas in the draft background paper.

Further underscoring the need to move away from Codex consideration of vitamin/mineral guidelines is the fluidity of the differing approaches in a number of countries or regions. For example, the European Union is considering the need for a food or dietary supplement directive, Japan is considering changes in how it classifies nutritional supplements, and Canada is looking at new approaches for natural health products. To interject a Codex guideline prior to governments for leading national or regional economies coming to their own policy conclusions would be counterproductive.

In the sections that follow, we comment in turn on each of the eight topics FDA identified in its Federal Register notice.

**1. Terminology.** The differing laws of various countries apply different terms for what the U.S. Food, Drug and Cosmetic Act (FDCA) defines as "dietary supplements" (even in English, let alone translations from other languages that may or may not literally translate to such a specific, precise English-language term). What fits under a "dietary supplement" umbrella varies even more dramatically among countries. As FDA notes in the Federal Register notice, the background paper under discussion will consider only issues relevant to vitamin and mineral supplements, and not products containing other ingredients or substances, such as herbs or other botanicals. From our view, FDA is precisely right: if the focus is squarely on vitamin and mineral products, then use that term. An exercise that tries to go beyond the issues at hand by defining a wider array of terms known to have varying meanings would be unproductive and invites debates that are not on point to an area that has already generated extensive Codex debate.

**2. Purpose and role of vitamin and mineral supplements.** Given past discussions of the CCNFSDU, we question the usefulness of this topic. As with definitions, varying countries have varying approaches to what constitutes an intended use – i.e., a purpose or role – which can

trigger different regulatory approaches by making a product a drug as opposed to a vitamin/mineral supplement. Under the FDCA here in the U.S., a vitamin/mineral supplement might have a role tied to a specific, classical nutrient deficiency *disease*, it might have a role tied to a specific *health-related condition* or a disease other than a classical nutrient deficiency (i.e., health claims), it might have a role intending to affect human *structure or function*, or it might have a *generalized health* optimization role. As FDA implies in its Federal Register notice, even if a Codex guideline did not directly change how vitamin/mineral supplements may describe their purpose or role in the U.S., an added barrier to U.S. exports could arise if a country adopted a more restrictive approach because of a Codex guideline.

Because the purpose or use of a product is so closely linked to its regulatory status as a food, supplement, "quasi-drug" (as some products are categorized in Japan), or drug, we do not believe it is constructive to seek to reconcile these approaches through a Codex guideline. We continue to believe the U.S. Government's stance (as well as the earlier stances of Australia and Japan) is the correct one: defining the purpose and role of vitamin/mineral supplements should be left to national authorities to regulate.

**3. <u>The concept of "approved nutrients."</u>** As CHPA has noted in comments to FDA prior to earlier CCNFSDU consideration of the subject (see CHPA [formerly NDMA] comments to Dr. Elizabeth Yetley, FDA, October 18, 1995, for example), there is no compelling public health reason to mandate a list of "approved" nutrients. Any static list of approved ingredients could have the perverse impact of denying consumers nutrient ingredients when new nutritional, scientific information was developed on ingredients not on the list. Consumers should be permitted to have access to supplements containing safe ingredients beneficial to human health whether or not they are on a Codex list. As with a number of other topics, we question the need for the topic and whether or not various differing viewpoints could be reconciled within the CCNFSDU.

**4. <u>Maximum levels for vitamins and minerals</u>.** Because maximum levels for vitamins and minerals are so closely tied to a product's regulatory status as a food, a supplement, a quasi-drug, or a drug in a number of countries, we again question how constructive it is to include this topic in any CCNFSDU guidelines. Nutrition science, attitudes toward optimal health, and scientific support for various roles for certain vitamins and minerals in human health is evolving

and will continue to do so. Recommended levels of nutrients should therefore remain flexible and be open to adjustment. We recognize, of course, upper or maximum levels are needed to protect public health on some nutrients on a case-by-case basis. But moving beyond such a case-by-case approach is highly likely to circle back to the recurring theme in these comments: definitions drive regulatory status categorizations; these categorizations trigger very different regulatory requirements; and since countries differ widely in these fundamentally different categorizations, consumers are best served by having their own national authorities make such categorizations, not through an international guideline.

**5. Minimal limits for vitamins and minerals.** We are unclear as to the purpose of this topic. Presumably, the claim structure for vitamin/mineral supplements, as described under the purpose/role topic, would drive any minimum limits. And since claims structures vary widely, a preferred resolution of this topic would be to remove it.

**6. Purity and Good Manufacturing Practices.** While we question the current need for CCNFSDU guidelines on vitamin/mineral supplements, this particular topic may be worth further discussion. Basic standards to assure that consumers are provided with products that have appropriate quality assurances could be commonly explored and provide a benefit to all concerned. As the U.S. Government continues to work on its background paper, develops its positions before the CCNFSDU meeting, and continues consideration of FDA's Advance Notice of Proposed Rulemaking on GMPs for dietary supplements here in the U.S., we would welcome opportunities for further dialogue on this topic.

**7. Labeling, warning statements, and claims.** As with the purpose/role topic, this area is core to how a national authority categorizes a product to begin with: foods, supplements, quasi-drugs, drugs, etc. Even within the European Union, where Member States are applying the same definition of medicinal product under Council Directive 65/65/EEC, how the various Member States categorize a product varies. Much of this variance is in turn tied to claims (as well as maximum level determinations or dosage form determinations). If 15 EU Member States with the same general end in mind and with a goal of a single market, using the same definition for what a medicinal product is (and, by negative implication, what isn't a medicinal product, thus opening food and vitamin/mineral supplement possibilities), can't agree on a product's classification, how realistic is it to expect a constructive discussion of claims within CCNFSDU?

**8. Packaging and marketing.** While the Codex Alimetarius Commission can play a valuable role in developing standards or guidelines to both protect human and animal health and to facilitate trade, we fail to see how it can play any constructive role for vitamin/mineral supplements on a packaging and marketing topic. Over extended periods of time, countries have evolved very differently in packaging and marketing practices, including available channels for product distribution. For example, many European countries and Japan restrict certain health-related products to pharmacies-only. The size of a package or dosage form presentation can similarly trigger distribution restrictions and change labeling requirements. Many of these differences inextricably tie to our recurring theme: definitions drive categorization; categorization drives regulatory approaches that vary widely. While it might seem easy to suggest that others follow the approach of the U.S., we recognize that is simply not a practical, considered objective. National authorities are better placed to consider and respond to the needs of their citizens on this topic, not an international standard-setting body.

**Conclusion.** At the present time, there is little visible international common ground on these vitamin/mineral supplement Codex topics. In drafting a background paper for the CCNFSDU, we encourage the U.S. Government to note the overarching difficulties in addressing these topics and, therefore, the need to decide to move on to other more constructive areas.

We appreciate the opportunity to submit these comments, and thank you for considering our views.

Sincerely,

David C. Spangler
Vice President – International
& Assistant General Counsel

cc: Robert J. Moore, CFSAN (HFS-456)

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